REMARKS

This paper is responsive to the Office Action mailed February 23, 2009. In the Office Action, the Examiner issued a non-final rejection of claims 1-10. Claims 11-20 had previously been withdrawn from consideration due to a restriction requirement.

In this paper, previously withdrawn claims 11-20 have been cancelled. New claims 21-30 have been added to the case.

35 USC 103(a) rejections:

Claims 1-10:

Claims 1-10 were rejected under 35 USC 103(a) as being unpatentable over applicant's admitted prior art (AAPA) (specification pages 1-3) in view of van Muiden (EP 0662385).

As stated in the specification, the prior art referenced by Applicant is generally discussed in the incorporated-by-reference U.S. Patent No. 5,380,304. As described therein, multi-layer introducer sheaths commonly utilized in the art are generally constructed by placing an inner liner material over a mandrel, positioning a braid or a coil over the outer surface of the inner liner, and positioning an outer thermoplastic material over the braid or coil. The assembly is placed in a heat shrink enclosure, and baked in oven to cause the thermoplastic outer layer to melt and flow between the wires of the braid or coil, such that it bonds to the inner liner.

Generally, it is desirable to maintain the wall thickness of an introducer sheath as small as possible. In this manner, the largest possible device can be passed into a body vessel through the smallest possible entry hole. Although the coil-reinforced prior art device (AAPA) referenced in the Background of the present application has a relatively thin wall, medical device designers are constantly searching for ways to reduce the wall thickness even more. In addition, as further stated in the Background (paragraph [0005]), on some occasions it is desirable to incorporate both a braid and a coil reinforcement into a sheath, and yet maintain a low sheath profile. (paragraph [0023]).

Those skilled in the art recognize that a braid is typically utilized to enhance torque control, whereas a coil is typically utilized to enhance the kink resistance of the sheath. (paragraph [0003]). Combining these two reinforcements in a single sheath provides enhancements to both torqueability and kink resistance. However, utilizing both reinforcements in an intermediate layer results in a structure that may be too thick-walled for some proposed uses. In addition, the wire or monofilament layers are susceptible to interfering with each other, in which case the resulting device may have neither good torqueability nor good kink resistance. (paragraph [0005]).

The present application addresses the problems of providing a thin-walled sheath. The application also addresses the problems of providing a thin-walled sheath capable of exhibiting the beneficial features of both a braid (torqueability) and a coil (kink resistance).

Claim 1 is directed to a method of manufacturing an introducer sheath. The method includes the steps of positioning a first polymeric sleeve over a mandrel, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve; positioning a second polymeric sleeve over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve, the first and second polymeric sleeves being axially aligned such that the second striped extrusion is superposed over the first striped extrusion to define a generally braid-like configuration; and heating the first and second polymeric sleeves.

According to the Examiner, AAPA teaches positioning a sleeve over a mandrel and heating the mandrel. However, the Examiner has acknowledged that AAPA does not teach multiple sleeves with helical stripes. As such, the feature of incorporating a braid into a sheath in this manner is not derivable from AAPA.

Van Muiden was cited for teaching positioning a first sleeve with a striped helical pattern and positioning a second sleeve with a striped helical pattern over the first sleeve. According to the referenced portions of van Muiden, an extrusion profile 30 is made up of two coaxial layers 31, 32, each having a number of extruded helically shaped bands of material. The bands of material 33 in the outermost layer

31 are running in the opposite direction to the helically shaped bands of material 34 in the innermost layer 32. According to van Muiden, a bond can be formed between the two layers with the helically shaped layers of material formed inside. However, as shown in Fig. 4 of van Muiden, the sheath maintains the integrity of layers 31, 32. Thus, even though van Muiden recognizes the trend toward ever thinner catheters (Col. 1, lines 17-20), in the cited embodiment of Fig. 4, van Muiden maintains two separate layers in order to provide his substitute for a braided reinforcement. This teaches away from the desire to provide a sheath having as small a wall thickness as possible.

Unlike either of the cited references, the method of claims 1-10 addresses the problem of providing torque control in a thin-walled sheath by positioning dual polymeric sleeves over a mandrel in the manner described above, and then heating the sleeves as described. The sleeves melt together into an outer layer having the superposed striped extrusions that define the braid. As the Examiner has noted, AAPA does not teach such multiple sleeves with helical stripes. Thus, the braid-like feature that provides torqueability to the sheath is not achieved in the low-profile sheath resulting from the prior art method. Similarly, van Muiden does not teach melting the two outer layers (31, 32) to obtain the low profile that he refers to as a desirable feature. Rather, by maintaining two outer layers, he teaches away from the desirability of providing a sheath having as small a wall thickness as possible.

The test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference, but rather, what the combined teachings of the references would have suggested to those of ordinary skill in the art. See, e.g., *In re Keller*, 642 F.2d 413 208 USPQ 871 (CCPA 1981). "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)). Similarly, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in

the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *KSR at 1741.*

Applicant respectfully submits that the present claims are not obvious in view of the cited combination. Each of the references recognizes the desirability of providing a low profile sheath having enhanced torqueability and/or kink resistance; however, the references do not teach or suggest the solution to the problem arrived at by the present claims. Although van Muiden includes some features in common with the claimed invention, the cited embodiment maintains dual outer sleeves in a manner that does not advance the desire of maintaining a low wall thickness. Applicant submits that no articulated reasoning with rational underpinning has been provided to support the obviousness finding.

In addition to the foregoing, Applicant points out that the Examiner must, of course, be aware of the distortion that can be caused by hindsight bias, and must be cautious of arguments reliant upon *ex post* reasoning. *KSR at 1742.* The proper question is whether the improvement is more than the predictable use of prior art elements according to their established functions. *KSR at 1740.* Applicant respectfully submits that it is only after the benefit of Applicant's disclosure is gained that the features of the invention may appear "obviousness". Neither of the citations teaches or suggests the manner of incorporating a braid-like configuration into a thin-walled sheath as claimed, not is the solution to this problem derivable from the teachings, either individually or in combination.

Claims 21-30:

New claims 21-30 have been added to the case. Applicant respectfully submits that these claims are also not obvious in view of the citations. Claim 21 is an independent claim, and claim 22-30 depend, directly or indirectly, from claim 21.

New claim 21 is directed to a method of manufacturing an introducer sheath. An inner liner is positioned over a mandrel, and a coil is positioned over the mandrel.

A first polymeric sleeve is positioned over the coil, the first polymeric sleeve comprising a first striped extrusion arranged in a generally helical pattern along the first sleeve. A second polymeric sleeve is positioned over the first sleeve, the second polymeric sleeve comprising a second striped extrusion arranged in a generally helical pattern along the second sleeve. The second striped extrusion has a pitch generally opposite a pitch of the first striped extrusion. The second sleeve is aligned over the first sleeve such that upon a melting of the sleeves the second striped extrusion is superposed over the first striped extrusion, and a generally braid-like configuration is defined thereby. A heat shrink material is positioned over an assembly comprising the mandrel, inner liner, coil, and first and second sleeves. The assembly is heated to a temperature sufficient to cause the heat shrink material to shrink, wherein the first and second sleeves melt together to form an outer tubular layer and to define the generally braid-like configuration therein, and the heat shrink material causes the outer tubular layer to bond to the inner liner through the coil turns.

The steps of this claim are generally illustrated in the sequence of Fig. 6 of the present application, and discussed in the related portions of the specification. At a minimum, the cited art does not teach or suggest the feature of combining first and second sleeves having respective striped extrusions as described over an inner liner and a coil, and melting the first and second sleeves in a heat shrink enclosure to form an outer tube (e.g., paragraphs [0029] and [0032]). In this manner, a sheath having a thin wall is obtained, wherein the thin-walled sheath also has both enhanced kink resistance (coil) and torqueability (braid).

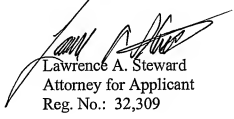
The claims depending from claim 21 describe other possible features of the inventive method. For example, according to claim 23, the first striped extrusion is provided along an outer surface of the first polymeric sleeve, and the second striped extrusion is provided along an inner surface of the second polymeric sleeve. In this way, the stripes can be in intimate contact following melting of the sleeves to provide a braid-like configuration that more closely resembles a braid of conventional wire or monofilament construction (paragraph [0043]). Claims 24, 25 and 30 describe other possible features of the extrusion process. Claims 26 and 27 describe the feature

wherein one or both sleeves includes at least two as sleeve segments (Fig. 7). Claims 28 and 29 describe possible compositions of the sleeves and extrusions. These claims are also believed to be nonobvious in view of the cited art.

Conclusion:

Based upon the foregoing, Applicant respectfully submits that the grounds for rejection of the claims have been overcome, and that all claims 1-10 and 21-30 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a timely notice of allowance. If the Examiner believes that further prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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